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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MOORE, WILLIAM W

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 01/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/978,385

Applicant(s)

PIDDINGTON ET AL.

Examiner

William W. Moore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2004 and 06 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 13, 14 and 16-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-12 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Response to Amendment

Applicant's Amendment filed March 4, 2003, amending claim 15 to exclude non-elected subject matter, has been entered. Claims 1-20 remain in the application where
5 claims 1-6, 13, 14, 17 and 18 were withdrawn from consideration by Applicant in the response to the requirement for restriction mailed August 27, 2002, as drawn to a non-elected invention.

Election/Restrictions

Applicant's election **with** traverse of Group II, claims 7-12 and 15, in the Paper filed
10 October 6, 2003, is acknowledged. This election is further to an election with traverse of three Groups, including Group II, in a Paper filed March 4, 2003, where the restriction between Groups II, VII and VIII and Groups I and III-VI was not traversed. Thus the only traversal of record is between the elected product of Group II encoding the human metalloprotease having the amino acid of SEQ ID NO:2 and the products of Groups VII
15 and VIII. Applicant's traversal of October 6, 2003, of the restriction requirement between Group II and Groups VII and VIII alleges that the human and murine metalloproteases share "significant structural similarity" that might allow "all three sequences to be searched at one time". This is not found persuasive because no formula is proposed for such a unitary search and because the likelihood that claims to
20 different products may present different issues of utility, adequate written description, scope of enablement, definite description, anticipation and obviousness over the prior art precludes any efficiency in the proposed joint examination of polynucleotides of the elected Group II encoding the human metalloprotease having the amino acid of SEQ ID NO:2 and polynucleotides of Groups VII and VIII encoding the murine metalloproteases
25 having the amino acid sequences set forth in SEQ IDs NOs:6 and 9, constituting an

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undue search burden. The requirement for restriction as between Group II and Groups I and III-VIII is still deemed proper and is therefore made FINAL. Claims 7-12 are examined herein, and claim 15 is examined to the extent that it describes compositions comprising vectors and viruses comprising polynucleotides of Group II.

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Notice of Requirements for Rejoinder

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The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.** Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

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Further, note that the prohibition against double patenting rejections of 35 U.S.C. §121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

35

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 15 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the absence of a designation in claim 15 of any particular Zace2-encoding nucleic acid sequence comprised by an expression vector, or recombinant virus comprising an expression vector, within the composition of claim 15, the claim must be construed to embrace compositions comprising expression vectors that, in turn, comprise nucleic acid sequences encoding Zace2 metalloproteases having the minimal structural feature the specification discloses to be exemplary of a claimed invention, the peptide regional "motif" set forth at page 4, lines 21-26, of the specification. Thus claim 15 contemplates compositions comprising expression vectors, or recombinant viruses comprising such vectors, that comprise polynucleotides encoding metalloproteases wherein all but 29 amino acid positions may be arbitrarily assigned, amounting to only about 4% of the overall amino acid sequence of an encoded metalloprotease by comparison with the 738-amino acid sequence of any of the human Zace2 metalloprotease having the amino acid sequence of SEQ ID NO:2. Claim 15 thus reaches compositions that comprise expression vectors or recombinant viruses comprising polynucleotides encoding generic proteins that may differ at as many as 96% of the amino acid positions in the amino acid sequence of SEQ ID NO:2 yet specification fails to exemplify or describe preparation of the subject matters of polynucleotides encoding such widely divergent metalloproteases and neither the claims nor the specification describe where the differences occur nor what the differences might be. "While one does not need to have carried out one's

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invention before filing a patent application, one does need to be able to describe that invention with particularity" to satisfy the description requirement of the first paragraph of 35 U.S.C. § 112. *Fiers v. Revel v. Sugano*, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993). In addressing the issue of whether a disclosure of a molecular structure of one polypeptide of one biological species could adequately describe the molecular structure of a functionally similar molecule of another biological species, the Court of Appeals for the Federal Circuit held that a claimed invention must be described with such "relevant identifying characteristic[s]" that the public could know that the inventor possessed the invention at the time an application for patent was filed, rather than by a mere "result that one might achieve if one had made that invention". *University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Indeed, claim 15 rejected herein is, like the claims invalidated by the appellate panel in *University of California v. Eli Lilly*, designed to embrace other, undisclosed, polynucleotides encoding yet unknown human polypeptides. Nothing demonstrates that, at the time the specification was filed, Applicant was "able to envision" enough of the structure of any of these myriad undisclosed polypeptides to provide the public with identifying "characteristics [that] sufficiently distinguish it . . . from other materials". *Fiers*, 25 USPQ2d at 1604 (citing *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991)). The specification's treatment of the claimed subject matter construed according to the definition at page 4, lines 21-26, is considered to be entirely prospective where skilled artisans in the relevant field of molecular biology could not predict the structure, or other properties, of metalloproteases encoded by the generic polynucleotides comprised by vector or virus components of compositions of claim 15.

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 7-12 and 15 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7-12 are rejected because claims 7 and 18 are indefinite in reciting, in clauses (c) of both claims, the term, "under stringent wash conditions", where many wash conditions are known in the art to be stringent and the artisan and the public seeking to determine the scope of the claims cannot know with certainty the degree of nucleotide sequence identity Applicant intends to define with the term. Claims 8-12 are included in the rejection of claim 7 because they depend therefrom thus incorporate its indefinite scope. Claim 15 is rejected because it specifies neither the amino acid sequence of a disclosed Zace2 metalloprotease using a sequence identifier – a "SEQ ID NO" – nor by any degree of relationship to a disclosed metalloprotease using a sequence identifier. Thus the public seeking to determine the scope of the claim cannot know with certainty the nature of the intended subject matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 7-12 and 15 are rejected under 35 U.S.C. § 102(e)(2) as being anticipated by Acton et al., U.S. 6,194,556, made of record herewith.

Acton et al. disclose, see Figures 1A and 1B, SEQ IDs NOs:1-3, and cols. 3, 4, 12, 13, particularly sentences at lines 18-29 of col. 13, 16, 17, and 29-30, the subject


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matters of claims 7-12 and 15 where human metalloprotease-encoding polynucleotides of SEQ IDs NOs:1 and 3 of Acton et al. encode the "Zace2" human metalloprotease having the amino acid sequence set forth in SEQ ID NO:2 herein.

Conclusion

5 Any inquiry concerning this communication or earlier communications from the
examiner should be directed to William W. Moore whose telephone number is
703.308.0583 until about January 21, 2004, and will be 571.272.0933 thereafter. The
examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to
10 reach the examiner by telephone are unsuccessful, the examiner's supervisor,
Ponnathapura Achutamurthy, can be reached at 703.308.3804 until about January 21,
2004, and at 571.272.0928 thereafter. The fax phone numbers for all communications
for the organization where this application or proceeding is assigned is 703.872.9306.
Any inquiry of a general nature or relating to the status of this application or proceeding
15 should be directed to the receptionist whose telephone number is 703.308.0196.

William W. Moore
January 5, 2004


NASHAAT T. NASHED PHD.
PRIMARY EXAMINER